510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

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510(k) FIRM CONTACT: Al Lippincott
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AUG 07 2013

DATE: June 10, 2013

TRADE NAME: **I.T.S. Extremity Fixation Systems**

COMMON NAME: Bone Plate, Bone Screw, Compression Screw - Systems

CLASSIFICATION: Plate, Fixation, Bone & Screw, Fixation, Bone

Smooth or threaded metallic bone fixation appliances and accessories. (*see 21 CRF, Sec. 888.3030*)
Smooth or threaded metallic bone fixation fastener, (*see 21CFR, Sec. 888.3040*).

DEVICE PRODUCT CODE: **HRS**

SUBSEQUENT PRODUCT CODE: **HWC**

SUBSTANTIALLY EQUIVALENT DEVICES
Ortho Solutions – Extremity Fixation Implants (**K111678**)
Stryker – Foot Plating Systems (**K060613, K063875**)
Memometal - Anchorage Bone Plate System (**K083447**)
Smith & Nephew – VLP Variable-Angle System (**K090675**)
Synthes – 2.4/2.7mm Variable Angle (VA)-LCP Forefoot / Midfoot System (**K100776**)
Vilex – Cannulated Dual Thread Screws (**K014154**)
Memometal – FIXOS Compression Screws (**K070039**)
Merete Medical – Cannulated HCS Compression Screws (**K091798**)
Integra – QWIX Fixation Screws (**K071639**)
Arthrex – Low Profile Plate and Screw System (**K052614**)
SBI – ForeFIX II (**K071479**)
Biomet – BioDrive Micro Nail Plate (**K092670**)
Memometal – FIXOS Twist-Off Screw (**K070039**)
Wright Medical – Charlotte Snap-Off Screws (**K050819, K043583**)

DEVICE DESCRIPTION: The *I.T.S. Extremity Fixation Systems* consists of Predicate extremity trauma implant components commonly found with large companies with orthopedic markets in the United States. These 'extremity trauma implant devices' consist of the following categories:

1. **FLS – Foot Locking Plates System**
2. **HCS – Headless Compression Screw System**
3. **HOL – Hallux Osteotomy Locking Plate**
4. **Twist-Off Screws**

A brief and concise description of each system is enclosed as follows:

1. FLS – Foot Locking Plates System: The *I.T.S. FLS – Foot Locking Plates System* is composed of various plate types(13) designed to address a wide variety of indications for fractures in the foot. The overall system is composed of a *smaller bone series of locking plates* (12 types) utilizing 2.4mm, 2.7mm and 3.0mm locking/non-locking screws and a larger bone calcaneus plate utilizing 3.5mm and 4.2mm locking/non-locking screws. The smaller bone system of twelve(12) plate designs consist of the following: (1) MTP Plate, (2) Curved Plate, (3) Straight Plate, (4) H-Shape Plate, (5) Square Plate, (6) L-Shape Plate, (7) L-Shape Extended Plate, (8) L-Shape Extended, 1mm Step Plate, (9) L-Shape Extended 45^0 Plate, (10) T-Shape Plate, (11) T-Shape Extended Plate, and (12) TMT Plate. The *larger bone system* consists of a (13) Calcaneus Plate. All plate systems are manufactured from Commercially Pure (CP) Titanium material to ASTM F67 and allow for minor intra-operative forming/ contouring by the surgeon to fit the bone anatomy. All screws consist of 6-4 Alloyed Titanium material to ASTM F136. Small holes in the plate allow intermediate 'k-wire' bone fracture segment positioning for reducing and aligning the fracture bone segments while positioning the plate and introduction of multiple sizes of locking/non-locking screws as needed for stabilizing the fracture – when using x-ray fluroscopy. All I.T.S. Plates and Screws are processed with an anodize DOTIZE surface treatment. The low-profile and contoured plate design minimizes soft-tissue irritation for the patient.
Associated instrumentation such as disposable drills, mills & wires/guide wires, and ancillary instrumentation is available. All plates and screws are provided **Non-Sterile**.

2. HCS – Headless Compression Screw System: The *I.T.S. HCS - Headless Compression Screw System* consists of six(6) sizes of compression screws (in sizes 2.0, 2.5, 3.0, 3.5, 4.3 and 7.5mm) for small bone extremity and large/long bone reconstruction fixation/arthrodesis procedures. All screws consist of a 6-4 Alloyed Titanium material to ASTM F136. All I.T.S. Compression Screws are processed with an anodize DOTIZE surface-treatment.
Associated instrumentation such as disposable wires/guide wires, cannulated spiral drills, countersink drills, and ancillary instrumentation is available. All screws are provided **Non-Sterile**.

3. HOL - Hallux Osteotomy Locking Plate: The *I.T.S. HOL – Hallux Osteotomy Locking Plate* consists of a Nail Plate in three(3) sizes with Screws in various lengths for Halux and distal metatarsal foot/toe bone deformities. The Nail Plate is manufactured from CP Titanium to ASTM F67 and the Screws from 6-4 Alloyed Titanium to ASTM F136. All I.T.S. Nail Plate and Screws are processed with an anodize DOTIZE surface treatment.
Associated instrumentation such as guide wire, disposable drill, template, insertion/removal and ancillary instrumentation is available. All Plates and Screws are provided **Non-Sterile**.

4. Twist-Off Screws: The *I.T.S. Twist-Off Screws* consist of a 2.0mm and 2.7mm twist-off shank screws in various lengths. All Turn-Off Screws are manufactured from 6-4 Alloyed Titanium to ASTM F136 and are utilized in metatarsal/phalangeal small bone fixation/osteotomy procedures. All I.T.S. Twist-Off Screws are processed with an anodize DOTIZE surface treatment. All Screws are provided **Non-sterile**.

INTENDED USE:

The ***intended use*** of the *I.T.S. Extemity Fixation Systems* is to draw two or more aligned bone fragments together to facilitate healing in an adult patient and is composed of the following catagories:

The *I.T.S. FLS – Foot Locking Plates System* **is indicated for use** in internal fixation, reconstruction or arthrodesis of small bones including the fore, mid and hind foot and ankle. Examples of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and treatment of fractures. Not for spinal use.

The *I.T.S. HCS – Headless Compression Screw System* for *sizes of 3.5mm or smaller* **is indicated for use** in fixation small bone fractures or for small bone reconstruction including: mono or bicortical osteotomies in the foot or hand; distal or proximal metatarsal or metacarpal osteotomies; weil osteotomy; fusion of the first metatarsalphalangeal joint and interphalageal joint; fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.); Akin type osteotomy; distal radius fractures (articular fragments), ulnar styloid fractures, radial head fractures, capitellum fractures, humeral head fractures, glenoid fractures, intercarpal distal and proximal fusions, malleolar fractures, patellar fractures, osteochondral fractures, talonavicular fusions, tibeo-talar fusions, and cuboid fusions. And for *sizes 4.3mm or larger* **is indicated for use** for fractures, corrective osteotomies, pseudoarthrosis, degenerative transformations of long bones in the hindfoot and large bone intra-articular fractures of the humerus, femur, and tibia. The size of the chosen compression screw should be adapted to the specific indication. Not for spinal use.

The I.T.S. HOL – Hallux Osteotomy Locking Plate System **is indicated for use** as an intramedullary self-locking plate for distal metatarsal osteotomies and for Hallux Valgus osteotomies up to a corrective angle of 25^0. Not for spinal use.

The I.T.S. Twist-Off Screw System **is indicated for use** for small bone fixation of bone fractures or for bone reconstruction. Examples include small bone fragments, Weil-Osteotomy, Mono-Cortical fixation, Osteotomies and fractures fixation in the foot and hand. Not for spinal use.

EQUIVALENCE:

The I.T.S. Extremity Fixation Systems are substantially equivalent to the varoius predicate bone plate and screw systems as listed. No nonclinical testing was used in the determination of substantial equivalence.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The I.T.S. Extremity Fixation Systems are Similar in Material, Geometry Design/Markings, and Indications to predicate system(s) currently sold in the U.S. market.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The I.T.S. Extremity Fixation Systems are shown to be safe and effective for use in plate and screw fracture fixation of small bones in the foot and hand extremities and screw compression fractures in long/large bones.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 7, 2013

I.T.S. GmbH
% Engineering Consulting Services, Incorporated
Mr. Al Lippincott
United States Agent and Official Correspondent to I.T.S. GmbH
3150 East 200th Street
Prior Lake, Minnesota 55372

Re: K131722
Trade/Device Name: I.T.S. Extremity Fixation Systems
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: June 26, 2013
Received: June 28, 2013

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) NUMBER: K131722

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The I.T.S. Twist-Off Screw System **is indicated for use** for small bone fixation of bone fractures or for bone reconstruction. Examples include small bone fragments, Weil-Osteotomy, Mono-Cortical fixation, Osteotomies and fractures fixation in the foot and hand. Not for spinal use.

Prescription Use XXXX AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices